

The statistical methods which appeared in the 1964 report, reappear in the 1967 one. A second article criticizing the methods is appended (from the Bulletin of National Statistical Institute, pp 856-860, 1966).

A CRITIQUE ON THE REPORT OF THE SURGEON GENERAL'S ADVISORY COMMITTEE ON SMOKING AND HEALTH

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ABSTRACT

The Report of the Surgeon General's Advisory Committee on Smoking and Health was first issued in January 1964 by the United States Public Health Service.

The critique submitted for presentation by the author is only part of a much longer version. In other words, the Report of the Surgeon General's Committee lends itself to a considerable amount of discussion.

Are the conclusions of the Surgeon General's Committee justified? The author feels that they are not and he bases that opinion on an examination of the methods employed by the Committee in arriving at its conclusions, the character of the Report itself and the composition of the Committee as far as scientific disciplines are concerned. In that respect, his critique can be summarized as follows:

1. In its Report, the Surgeon General's Committee did not make a clear distinction between *causal significance* and *proof* and, on one occasion, did use the terms interchangeably.

2. It organized the evidence poorly, so poorly, that it is not difficult for one, in reading the Report, to lose sight of the objectives.

3. It did not use a systematic approach in investigating various aspects of the problem.

4. It failed frequently to offer reasonable or meaningful definitions of statistical and epidemiological terms. An outstanding example of this is given on page 3 of the critique.

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5. It was not altogether consistent in applying principles.
6. Its criteria for judging causation were not entirely realistic. In fact, with one exception, those criteria could be better described as criteria for ascertaining the value of a variable as a *diagnostic index*, a *predictor*, or both.
7. It engaged in a considerable amount of rationalization with respect to evidence which did not conform to the particular hypothesis which it had chosen to explore in detail. On the other hand, it appeared to be more convenient for the Committee to downgrade evidence which was consistent with another hypothesis than for it to change its policy and explore that hypothesis in detail as well.
8. Its Report is replete with redundancies. Indeed, there are instances in which the paraphrasing is such that one is left with the impression that new pieces of evidence were being introduced.
9. It did not distinguish between *primary* and *secondary* cancer of the lung, and such a distinction is essential, since cigarette smoking or not smoking is not assumed to be related to the occurrence of secondary cancer of the lung.
10. Not all pertinent scientific disciplines were represented on the Committee. For example, there was no psychiatrist, psychologist, sociologist, geneticist or radiologist on the Committee.
11. The Committee did not appear to be consistently aware of the fact that *self-selection* is the one known *factor* which cannot be controlled completely in any survey regardless of form. Self-selection may be characterized in the following hypothesis:

Even if cigarette smokers, as a group, did not smoke, there still would be a higher proportion of persons with *primary* cancer of the lung, say, among them than among non-smokers, as a group, since constitutionally they are more disposed to the disease. That, of course, is a statement of the *constitutional hypothesis*.

By taking all of these criticisms and others into consideration, and by exploring the constitutional hypothesis in much greater detail than did the Surgeon General's Committee, the author is able to conclude that there is strong reason to believe that the evidence appearing in the Report of the Surgeon General's Committee fits the *constitutional hypothesis* at least as well as it does the *cigarette hypothesis*. That alone would suggest that a causal significance cannot be attached to the relationships mentioned at the outset of the critique, i.e., to the relationship between cigarette smoking or not smoking and the occurrence of certain respiratory diseases and to the relationship between cigarette smoking or not smoking and the occurrence of coronary heart disease. (It is not feasible to conduct studies of the type which would force these relationships to disappear if they are not those of cause and effect). Finally, more research would be necessary to test *definitively* the strength of one hypothesis against that of the other, and that is how the author feels the situation with respect to smoking and health stands at the present.

DISCUSSION

W. G. COCHRAN. As the statistician on the Committee whose report Dr. Saiger has criticized, I am a little hesitant to enter the discussion. The Committee studied the evidence for a year, with great assistance from a large panel of expert consultants. The Committee's report has 397 pages, and received widespread distribution and publicity. Consequently, there is merit in the point of view that the Committee has had its say, and that when critiques appear, the interested bystander can read the critique and the Report and form his own opinion.

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Further, the problem of the relation between smoking and health is one on which new data are continuously accumulating, particularly data on females, of which relatively little was available to the Committee, and further person-years of experience in the prospective studies, which facilitate the type of control on more variables that Dr. Saiger and I both favour. The most interesting question is not what the state of the evidence was early in 1963, when the Committee study was in progress, but what it is now. This, of course, gets beyond the scope of Dr. Saiger's paper.

Nevertheless, I would like to comment, for two reasons. Dr. Saiger's references to the Committee's work are inaccurate in a number of respects. I would like to quote two examples, to reinforce my hope that those who are interested in his arguments will read the relevant part of the report. Secondly, the problem of appraising the self-selection or constitutional hypothesis — the main theme of Dr. Saiger's paper — is a challenging one for statisticians.

First as regards inaccuracies. On pp. 6—7 Dr. Saiger doubts the competence and ability of the 10 men, and particularly of the poor statistician, to cover the vast literature on this problem in the time used. He omits to tell you of the 189 persons and agencies used as expert consultants, through these are listed and their contributions described right at the beginning of the Report.

At the top of page 3, Dr. Saiger refers to the committee's definition of a cause as being "a significant, effectual, relationship between an agent and an associated disorder or disease in the host", and proceeds to ridicule such a definition. In fact, the Committee gave no formal definition of a cause, recognizing that cause and effect are complex ideas, but instead discussed on pp 20—21 their conception of causality. The sentence from which Dr. Saiger purports to be quoting reads as follows (p.21). "The word *cause* is the one in general usage in connection with matters considered in this study, and it is capable of conveying the notion of a significant, effectual, relationship between an agent and an associated disorder or disease in the host". The Report goes on at once to state: "no member of this Committee used the word *cause* in an absolute sense in the area of this study" and "all members shared a common conception of the multiple etiology of biological processes".

As regards the self-selection hypothesis, I agree with Dr. Saiger that a well-planned, long-term randomized experiment would be enlightening but is impracticable. In appraising this hypothesis from non-randomized data, what can one do? To quote some of the statistical evidence for males, the death rate at a given age increases steadily with the number of cigarettes smoked. For men of a given age who report smoking the same amount, the death rate increases with the number of years smoked. For men of a given age who previously smoked a given amount, the death rate is lower for those who have stopped than for those who have continued. In two groups of men of the same age who have stopped for the same length of time, the group which previously smoked more have the higher death rate. Dr. Saiger seems to think that the self-selection hypothesis can comfortably accommodate all these results and others which I could cite. My opinion is that it is being stretched very thin.

Secondly, one considers all studies in which differences in physique, habits, ancestry, psychological pattern and so on between cigarette smokers and non-smokers have been examined. Dr. Saiger mentions, as does the Report, a number of variables in which differences have been found in some studies. However, these differences are at most small differences between the means of two populations that overlap extensively.

Thirdly, in the prospective and retrospective studies, one adjusts for any variables other than smoking that are known or suspected to be related to the probability of dying. In the analyses leading to the Report, these adjustments were computed wherever the data allowed it. Except for age, for which adjustment is essential, these computations produced only slight changes in the mortality ratio. On page 13, in mentioning a seven — variable adjustment by Hammond, Dr. Saiger points out that the 7 did include important variables such as longevity of parents and grandparents, initial health status of the subject, marital status, and so on. Actually, Hammond already examined the effects of adjusting for each of these variables individually, again finding only slight changes in the mortality ratio. From inspection of Hammond's data, my judgement was and is that the combination of variables would give essentially the same conclusion.

From all this, the Committee reached the judgement that self-selection could account for only a minor fraction of the observed difference in death rates. It felt in no position to put a precise figure, say 5% or 15%, on this fraction, and like Dr. Saiger, I look forward to seeing more data bearing on the constitutional hypothesis. I feel, however, that the extreme form of the constitutional hypothesis cannot be appraised by these methods. No matter for how many variables we adjust, the objection can be raised that the difference in death rates is due to some further variable not yet measured.

Finally, my opinion is that the new data that I have seen since 1963 do not weaken the main conclusions of the Report.

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V. G. PANSE. A sample survey cannot provide rigorous evidence of cause and effect relationships, irrespective of how many variables are controlled, since factors affecting observed phenomena are almost innumerable. At best, the results can indicate possible lines for further investigation. Some years back Prof. Fisher offered the hypothesis that persons who were genetically more prone to cancer developed a craving for smoking. Neither this nor any other hypothesis can be tested by sample survey. It requires experimentation by randomization of experimental units. Since this does not seem feasible when dealing with human beings, data obtained from experiments on laboratory animals should be very valuable ancillary evidence. Correlations observed in sample surveys should not be taken for cause and effect relationships but as indications which can be tested unequivocally only by experimentation.

G. L. SAIGER. Thank you, Prof. Cochran, for your comments. These are my comments in turn:

1. I should like to urge those who are interested in the problem of whether or not smoking affects health adversely to read the full text of my critique as well as the Report of the Surgeon General's Committee. One ought not to consider my summary, Prof. Cochran's comments and my rebuttal sufficient for the purpose of forming an opinion of his own.

2. Additional evidence has accumulated since the Report of the Surgeon General's Committee was first issued. That evidence cannot alter the methods employed by the Committee in arriving at its conclusions, the character of the Report itself nor the composition of the Committee as far as scientific disciplines are concerned. Depending on its quality, I am willing to accept the evidence on which the Report was based and the new evidence for the purpose of testing the strength of the cigarette hypothesis against that of the constitutional hypothesis. I am convinced that all such evidence, old and new, fits the constitutional hypothesis at least as well as it does the cigarette hypothesis.

In speaking of new evidence, Prof. Cochran fails to mention those studies whose results suggest that, exclusive of changes brought about by the disease itself, persons with cancer of the lung have characteristics which are not the same as those of other persons. That is important, since we already know that cigarette smokers differ from non-smokers constitutionally.

3. Prof. Cochran speaks in generalities about alleged inaccuracies in my critique with respect to the work of the Committee, and then proceeds to give examples of two:

a) It should be emphasized that the number of articles and other sources of information which the Surgeon General's Committee was reported to have reviewed exceeded 10,000, and most of the evidence contained in those articles and other sources of information was statistical in nature. Prof. Cochran states that 189 persons and agencies were used as expert consultants by the Committee. As far as I can determine, there were only 31 statisticians in that group, and not all of them would be classified as experts. Though Prof. Cochran had not expressed an opinion publicly on the problem of whether or not smoking affects health adversely before being called on to assist in weighing the evidence, can the same be said of the statistical consultants? My point is this: Some of the statistical evidence contained in the Report of the Committee is not the kind of evidence which a man without bias and of Prof. Cochran's competence would have accepted, I am certain, had he ascertained the value of that evidence himself.

b) Prof. Cochran claims that the Surgeon General's Committee gave no definition of "a cause". To support that claim, he refers to the following sentence on page 21 of the Report of the Committee:

"The word *cause* is the one in general usage in connection with matters considered in this study, and it is capable of conveying the notion of a significant, effectual, relationship between an agent and an associated disorder or disease in the host".

There is no doubt in my mind but that "a significant, effectual, relationship between an agent and an associated disorder or disease in the host" is the Committee's definition of "a cause", however Prof. Cochran may choose to interpret it. Obviously, such a definition deserves to be ridiculed. Obviously, such a definition needs to be qualified, and the Committee did that, at least in part, by stating that it did not use the word "cause" in an absolute sense and by expressing a concern for the concept of multiple causation.

4. Indeed, I do feel that evidence acquired in epidemiological surveys and appearing in the Report of the Surgeon General's Committee is consistent with the constitutional hypothesis. May I quote from pages 11 and 12 of my critique with respect to that hypothesis:

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From page 11—

"... Once a person's constitution is determined, so are his degree of disposition to the practice of cigarette smoking and his degree of disposition to the disease, and those degrees are highly and *positively* correlated".

From page 12—

"A low degree of disposition to the practice would be exemplified by the person who discontinues it freely after starting late in life and smoking two or three cigarettes per day for two years without inhaling".

That the Committee was confused with respect to the concept of "degree" as opposed to the concept of "kind" is well illustrated on page 10 of my critique. May I quote further:

"... The Surgeon General's Committee assumed that two distinct makeups were required to explore the constitutional hypothesis, one for cigarette smokers and one for non-smokers. But that assumption is neither realistic nor consistent with other observations on constitution made by the Committee. For example, the Committee did not expect to find all males among cigarette smokers and no males among non-smokers. Yet sex is a constitutional factor. In a similar fashion, it should not have expected to find all neurotics in one group and no neurotics in the other, nor even a much higher proportion of neurotics in one group than in the other".

5. Prof. Cochran states that constitutional differences between cigarette smokers and non-smokers are at most small differences. Presumably, he derived that opinion from an examination of single variables. It is not unusual, with biological variables, to observe a considerable amount of overlapping of distributions. I already have alluded to that possibility in the preceding paragraph. Furthermore, I was able to increase estimated distances between the groups significantly by forming combinations of variables. That was one basis for the statement in my critique that constitution more adequately would be represented by a combination of variables. That was one basis for the statement in my critique, and in my summary, that it appeared to be more convenient for the Surgeon General's Committee to downgrade evidence which was consistent with another hypothesis than for it to change its policy and explore that hypothesis in detail as well.

And what does the Report of the Surgeon General's Committee show? It shows that longevity of parents and grandparents could have an appreciable effect on the overall relative risk of dying among cigarette smokers, and that health status of the subject at the beginning of the survey, marital status, whether or not tranquilizers were being used and degree of exercise are highly related to the probability of dying, i.e., they are known *factors* of importance in the occurrence of death. It also shows that Hammond did not include those factors in a combination. Prof. Cochran confirms that observation in his comments.

Hammond did include other factors in a combination, however, and his results indicate that age and sex are not the only factors which should be controlled in exploring the constitutional hypothesis. (Note: The Surgeon General's Committee controlled age and sex only in arriving at its relative risks). Prof. Cochran and I both agree that studies should be conducted in the area of controlling progressively larger combinations of variables. The constitutional hypothesis does not specify that, in epidemiological surveys, the point can be reached where the relative risks of dying would estimate unity. (The only way in which self-selection can be controlled completely is by means of a long-term human experiment). There is a strong possibility, however, that they would approach unity. If they did, then the conclusions of the Surgeon General's Committee would be weakened further rather than strengthened. Therefore, the statement by Prof. Cochran that "no matter for how many variables we adjust, the objection can be raised that the difference in death rates is due to some further variable not yet measured" is grossly misleading. For the same reason, I cannot agree with Prof. Cochran that the problem of exploring the constitutional hypothesis is a challenging one for statisticians.

6. There is an important piece of evidence which Prof. Cochran, as a member of the Surgeon General's Committee, fails to explain: Why is it that primary cancer of the lung, histologically similar to that found in humans, can be produced in animals and with a variety of substances, but, as far as is known, not with condensates of cigarette smoke?

Prof. Cochran's comments and my rebuttal may have created some misunderstanding. Therefore, in closing, let me state my position as follows:

I am not an advocate of the constitutional hypothesis. The chief purpose of my critique is to determine whether or not the conclusions of the Surgeon General's Committee are justified. In examining the methods employed by the Committee in arriving at its conclusions, I find that it should have explored more than one hypothesis in detail and I offer, as a logical alternative, the constitutional hypothesis.

Though Prof. Cochran and I disagree on many points we apparently do not disagree on an important one, namely on the need for more research to test further (or *definitively*, as I call it) the strength of the cigarette hypothesis against that of the constitutional hypothesis.

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